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10/599,015	11/19/2008	Tami Harel	298859-00012	3153

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EXAMINER

STICE, PAULA J

ART UNIT	PAPER NUMBER
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3766

NOTIFICATION DATE	DELIVERY MODE
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05/10/2012

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipmail@eckertseamans.com

Office Action Summary	Application No.	Applicant(s)	
	10/599,015	HAREL ET AL.	
	Examiner	Art Unit	
	PAULA J. STICE	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2012.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-7,10,13-26,28-45,47-59,61-73 and 75-83 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-7,10,13-26,28-45,47-59,61-73 and 75-83 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 18 September 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/15/2012; 2/23/2012; 11/27/2011;</u> | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 3/15/2012 with respect to the 35 USC rejections of claims 33-34 have been fully considered but they are not persuasive. Applicant argues, on page 14 that paragraphs [0673-0677] as well as Figs. 49A, 49B and 49C support the claim language. The claims read:

- Claim 33: A method, comprising: fixing at least two pairs of electrodes to a stomach site of a patient, in a longitudinal orientation with respect to a curved long axis of the stomach; and driving the electrodes to apply a signal to the site configured to treat a pathology of the patient.
- Claim 34: A method, comprising: fixing at least two pairs of electrodes to a stomach site of a patient, in perpendicular orientation with respect to a curved long axis of the stomach; and driving the electrodes to apply a signal to the site configured to treat a pathology of the patient.
- Claim 35: A method, comprising: fixing at least two pairs of electrodes to a stomach site of a patient, in mixed with respect to a curved long axis of the stomach; and driving the electrodes to apply a signal to the site configured to treat a pathology of the patient.

2. It is first noted that the limitation "curved long axis of the stomach" is not defined in the specification nor shown in the drawing, it is therefore impossible to determine what this is. Furthermore it is unclear how an axis can be curved; based on a standard X-Y axis orientation there is not curvature involved. These claims remain rejected in that it is impossible to ascertain what a "longitudinal orientation", "perpendicular orientation" or "mixed orientation" with respect to "a curved long axis of the stomach" can include or can exclude.

Art Unit: 3766

3. Applicant's arguments with respect to the claims has been considered but are moot because the arguments do not apply to any of the references being used in the current rejection.

Drawings

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the curved long axis of the stomach must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Regarding claims 16-21, 33-35, as well as their dependents 20-21, 36-49, 50-59, 61-63, 64-73 and 75-77 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the stomach, does not reasonably provide enablement for “a curved long axis of the stomach”. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The “curved long axis of the stomach” is not a standard physiological term, furthermore a longitudinal orientation with respect to an undefined term (i.e. curved long axis) does not reasonably provide enablement in that the exact method being performed, based on the claim language, cannot be ascertained.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-8, 10, 13-21 and 78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 3766

9. Regarding claim 1, the claim recites "the absence" in line 6 there is insufficient antecedent basis for this claim limitation. It is suggested that the word "the" is replaced with "a".

10. The remainder of the claims (i.e. 2-8, 10, 13-21 and 78) are also rejected in that they depend from a previously rejected independent claim.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1-8, 10, 33-39, 50-53, 64-67 and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flesler et al. US 6,600,953 _{in IDS} in view of Darvish et al. US 2003/0055464 _{in IDS}.

Art Unit: 3766

14. Regarding claims 1 and as best understood 33-37, 50-51 and 64-65: Flesler discloses electrodes adapted to be implanted in the stomach and the intestinal area of a patient (Figs. 1A, 1B and 4) and a control unit 90 (Figs. 1A, 1B) adapted to drive, even in the absence of a detection of eating by the patient a first subset of electrodes to apply a first signal (Col. 3, lines 65-67 and Col. 3 lines 1-25) and to drive, responsive to eating, a second subset of electrodes different from the first to treat obesity (Col. 4, lines 33-67). However, Flesler does not specifically disclose that the first signal delivered by electrodes implanted in the stomach or intestinal site is configured to reduce a blood glucose level. Darvish however teaches of a device which is to control blood glucose levels in a patient (Abstract) in which the device remains in the intestines, within a folded portion of the intestines with the electrodes in the vicinity of the pancreas in order to control and regulate insulin which in turn regulates glucose levels (pg. [0057]). It therefore would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the intestinal apparatus of Flesler (Fig. 4) to include electrodes which can stimulate the pancreas to regulate glucose, as taught by Darvish, in order to treat diabetes in a patient and/or regulate blood sugar levels.

15. Regarding claims 2-3: Flesler discloses that the control unit is adapted to drive the first subset and/or second subset as an ETC signal (Col. 2, lines 20-25 and Col. 3, lines 55-67 through Col. 4, lines 1-7).

16. Regarding claim 4: Flesler discloses at least one electrode in common, the sensing electrodes 72/74/70 (Figs. 1A, 1B) are all in common.

Art Unit: 3766

17. Regarding claim 5 : Flesler discloses that the first and second subsets are identical 30 (Figs. 1A, 1B), the electrodes themselves appear to be identical in shape and configuration.

18. Regarding claim 6: Flesler discloses that the first subset (within band 22) have no electrodes in common the electrodes on the pyloric sphincter are in a different area considered to not be in common or alternatively, the electrodes within the intestinal apparatus are not in common.

19. Regarding claim 7: Flesler discloses that the implantation site is the stomach (Figs. 1A, 1B) and the electrodes are adapted to be fixed to the stomach (Col. 9, lines 57-61).

20. Regarding claim 8: Flesler discloses the gastric antrum (Col. 1, lines 31-37) via incorporation by reference of patent number 5,423,872) as well as the general location of the electrode highlighted below, the electrode with the arrow included is within the region of the pyloric antrum as shown above.

21. Regarding claim 10: Flesler discloses an implant site includes an intestinal site (Fig. 4, Col. 13, lines 50-67), the electric field applied to the intestinal blood supply, considered to be an intestinal site reduces calories absorbed (Col. 14, lines 1-5).

22. Regarding claims 38, 52 and 66: Flesler discloses that the control unit is adapted to drive the first subset not responsive to eating (Col. 3, lines 14-19) and to drive a second subset responsive to eating (Col. 3, lines 19-25, it is noted that the subsets are not disclosed as differing in location with respect to claim 1, from which claim 11 depends.)

Art Unit: 3766

23. Regarding claims 39, 53 and 67 (as understood): Flesler discloses that the control unit drives the first subset responsive to eating (Col. 4, lines 50-58 and Col. 5, lines 13-24).

24. Regarding claim 78: Flesher discloses that the signals are delivered at different times (i.e. ETC and excitatory pulse, Col. 4, lines 20-67).

25. Claims 13-21 and 40-42, 54-56 and 68-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flesler et al. US 6,600,953 _{in IDS} in view of Darvish et al. US 2003/0055464 _{in IDS} and further in view of Foley US 2004/0162595 _{in IDS}.

26. Regarding claims 13-15 and 40-42, 54-56 and 68-70: Flesler/Darvish discloses the claimed invention however Flesler/Darvish does not specifically disclose two pairs of electrodes fixed to the antrum of the stomach. Foley however, teaches of a sensor based gastric stimulator (abstract) in which four or more bipolar (considered to be pairs of electrodes) are placed posterior and anterior in the antrum of the stomach (pg. [0075] and Figs. 1, 7, 8) in order to locate a stable position. It therefore would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Flesler/Darvish to include bipolar electrode pairs, as taught by Foley within the antrum of the stomach in order to have a sensing and pacing electrode pair as well as a stable location.

27. Regarding claims 16-21: see the 35 USC 112 rejections, the scope of the claims cannot be determined, furthermore the structure of the device cannot be determined; it

Art Unit: 3766

is believed by the examiner that the general structure disclosed is found in Flecher Figs. 1A-1B and Fig. 4.

28. Claims 22, 29-32, 43-44, 48-49, 57-58, 62-63, 71-72, 76-77 and 79-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flesler et al. US 6,600,953 in view of Darvish et al. US 2003/0055464 in IDS and further in view of Chen et al. US 5,690,691 in IDS.

29. Regarding claims 22, 31, 43-44, 57-58 and 71-72 (as understood): Flesler discloses electrodes adapted to be implanted in the stomach and the intestinal area of a patient (Figs. 1A, 1B and 4) and a control unit 90 (Figs. 1A, 1B) adapted to drive, even in the absence of a detection of eating by the patient a first subset of electrodes to apply a first signal (Col. 3, lines 65-67 and Col. 3 lines 1-25) and to drive, responsive to eating, a second subset of electrodes different from the first to treat obesity (Col. 4, lines 33-67). However, Flesler does not specifically disclose that the first signal delivered by electrodes implanted in the stomach or intestinal site is configured to reduce a blood glucose level. Darvish however teaches of a device which is to control blood glucose levels in a patient (Abstract) in which the device remains in the intestines, within a folded portion of the intestines with the electrodes in the vicinity of the pancreas in order to control and regulate insulin which in turn regulates glucose levels (pg. [0057]). It therefore would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the intestinal apparatus of Flesler (Fig. 4) to include electrodes which can stimulate the pancreas to regulate glucose, as taught by Darvish,

Art Unit: 3766

in order to treat diabetes in a patient and/or regulate blood sugar levels. Flesler/Darvish therefore discloses the claimed invention except a first frequency component for the first subset of electrodes and a second frequency component for the second subset of electrodes. Chen however discloses a device to aid in peristaltic movement (abstract) in which the upper portion of the stomach is paced at 3 cpm (180Hz) and the lower portion is paced at 12.5 cpm (750 Hz) (Col. 6, lines 43-55). It therefore would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Flesler/Darvish to include frequency differences to different parts of the stomach for stimulation purposes, as taught by Chen, in order to aid in peristaltic movement.

30. Regarding claims 83, 29, 30 and 32 and 48-49, 62-63 and 76-77 (as understood): Flesler/Chen disclose the claimed invention except for the first frequency component being less than 10 Hz and the second greater than 10 hz and between 60-100Hz and five time larger than the first component. It would have been obvious to one having ordinary skill in the art at the time the invention was made to the first frequency component being less than 10 Hz and the second greater than 10 hz and between 60-100Hz and five time larger than the first component, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

31. Regarding claim 79: Flesler discloses at least one electrode in common, the sensing electrodes 72/74/70 (Figs. 1A, 1B) are all in common.

Art Unit: 3766

32. Regarding claim 80 : Flesler discloses that the first and second subsets are identical 30 (Figs. 1A, 1B), the electrodes themselves appear to be identical in shape and configuration.

33. Regarding claim 81: Flesler discloses that the first subset (within band 22) have no electrodes in common the electrodes on the pyloric sphincter are in a different area considered to not be in common or alternatively, the electrodes within the intestinal apparatus are not in common.

34. Regarding claim 82: Flesher discloses that the signals are delivered at different times (i.e. ETC and excitatory pulse, Col. 4, lines 20-67).

35. Claims 23, 26, 28, 45, 47, 59, 61, 73 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flesler et al. US 6,600,953 _{in IDS} in view of Darvish et al. US 2003/0055464 _{in IDS} and further in view of Chen et al. US 5,690,691 referred to herein as Chen '691 _{in IDS} and further in view of Chen et al. US 2005/0021101 referred to herein as Chen '101 _{in IDS}.

36. Regarding claims 23, 26, 45, 59 and 73 (as understood): Flesler/Darvish/Chen '691 disclose the claimed invention except the use of a pacing pulse, Chen '101 however teaches of a pacing pulse in order to achieve antergrade electrical stimulation to normalize dysrhythmia (pg. [0074]). Chen '101 also discloses the use of pacing pulses to slow gastric emptying which will slow gastric emptying and result in weight loss (pg. [0080]). It therefore would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Flesler/Darvish/Chen '691 to include

Art Unit: 3766

pacing pulses, as taught by Chen '101 in order to either slow gastric emptying or normalize dysrhythmia.

37. Regarding claims 28, 47, 61 and 75 (as understood): Flesler/Darvish/Chen '691 discloses the claimed invention except for the first frequency signal following the pacing pulse by 500 ms. It would have been obvious to one having ordinary skill in the art at the time the invention was made to the first frequency signal following the pacing pulse by 500 ms, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

38. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Flesler et al. US 6,600,953 _{in IDS} in view of Darvish et al. US 2003/0055464 _{in IDS} and further in view of in view of Chen et al. US 5,690,691 referred to herein as Chen '691 _{in IDS} and further in view of Chen et al. US 2005/0021101 referred to herein as Chen '101 _{in IDS} and further in view of Ben-Haim et al. US 2003/0055465.

39. Regarding claim 46: Flesler/Darvish/Chen'691/Chen'101 disclose the claimed invention except stimulating during a refractory period. Ben Haim however teaches that applying a signal at a delay following the activation signal (during the refractory period) will extend the refractory period and thus result in decreased propagation of the signal and a reduced the force of contraction (pg. [0229]). It therefore would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Flesler/Darvish/Chen'691/Chen'101 to include stimulating during a refractor period, as

Art Unit: 3766

taught by Ben-Haim in order to extend the refractory period and thus decrease muscle contraction.

40. Claims 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flesler et al. US 6,600,953 _{in IDS} in view of Darvish et al. US 2003/0055464 _{in IDS} and further in view of Chen et al. US 5,690,691 _{in IDS} and further in view of Ben-Haim et al. US 2003/0055465.

41. Regarding claims 24-25: Flesler/Darvish/Chen discloses the claimed invention except the use of non-excitatory stimulation. Ben-Haim however teaches of using non-excitatory neural stimulation in a smooth muscle controller in order to avoid the propagation of an action potential buy yet modify the excitatory field (pg. [0013]). It therefore would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Flesler/Darvish/Chen to include the use of non-excitatory stimulation in order to avoid the propagation of an action potential buy yet modify the excitatory field.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

Art Unit: 3766

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAULA J. STICE whose telephone number is (571)270-1478. The examiner can normally be reached on Monday - Friday 8AM-5PM, Mst., alternating Friday's.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/599,015

Page 15

Art Unit: 3766

/PAULA J. STICE/

Examiner, Art Unit 3766

/CARL H LAYNO/

Supervisory Patent Examiner, Art Unit 3766